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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/731,261 | 12/06/2000 | Joel F. Habener | 17633/1230 | 9060 |

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ART UNIT PAPER NUMBER

1632 19
DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|---|--------------------------------------|--------------------------------|
| Office Action Summary | Application No. 09/731,261 | Applicant(s) Habener |
| | Examiner Anne Marie Wehbé | Art Unit 1632 |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | |
| Period for Reply | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | |
| <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | |
| Status | | |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jan 29, 2003</u> | | |
| 2a) <input type="checkbox"/> This action is FINAL . 2b) <input checked="" type="checkbox"/> This action is non-final. | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | |
| Disposition of Claims | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-41</u> is/are pending in the application. | | |
| 4a) Of the above, claim(s) <u>1-18 and 30-41</u> is/are withdrawn from consideration. | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>19-29</u> is/are rejected. | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | |
| 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement. | | |
| Application Papers | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | |
| 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. | | |
| 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | |
| 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | |
| Attachment(s) | | |
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>18</u> | | |
| 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | | |
| 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | | |
| 6) <input type="checkbox"/> Other: _____ | | |

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DETAILED ACTION

Applicant's response to the restriction/election requirement received on 1/29/03 has been entered. Applicant's election with traverse of the subject matter of Group II, claims 19-29, is acknowledged. Claims 1-41 are pending in the instant application. Of these, claims 1-18, and 30-41 have been withdrawn as being drawn to subject matter non-elected with traverse in paper no. 16. Claims 19-29 are currently under examination. An action on the merits follows.

Restriction

The applicant has elected the subject matter of Group II, claims 19-29, with traverse. However, the applicant has not provided any arguments regarding the grounds for restriction. The restriction requirement is therefore maintained for reasons of record as discussed in detail in the previous office action. Thus, requirement is still deemed proper and is made FINAL.

Priority

The applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: the applicant has failed to provide a specific

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reference to the provisional applications listed in the declaration as the first sentence of the specification following the title.

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the

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claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

As the applicant has not complied with conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e), the effective filing date is the actual filing date of the instant application, 12/6/00.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps include a step where by nestin positive cells are identified. In the absence of this step, cells which are nestin positive cannot be selected.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 22-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Stoffers et al. (2000), Diabetes, Vol. 49, 741-748. The applicant claims a method of inducing the differentiation of a nestin-positive pancreatic stem cell into a pancreatic progenitor cell by treating a nestin-positive pancreatic stem cell with an agent selected from a group which includes IDX-1. Please note that the applicant's claims as written read on the treatment of nestin-positive pancreatic stem cells both *in vivo* and *in vitro*.

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Stoffers et al. teaches the administration of GLP-1 *in vivo* resulting in the differentiation and proliferation of new β -cells derived from pancreatic ductal tissue (Stoffers et al., page 741, and page 745). While Stoffers et al. does not specifically teach that nestin-positive cells in the pancreas are contacted with GLP-1, pancreatic ductal tissue inherently includes nestin-positive cells. The fact that Stoffers teaches that ductal epithelia in the pancreas are affected by the administered GLP-1 indicates that nestin-positive cells inherently present in the pancreatic ductal tissue are contacted by the administered GLP-1. Thus, the process of inducing the differentiation of pancreatic ductal tissue by treatment with GLP-1 as taught by Stoffers et al. anticipates the instant invention as claimed. Please note that it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. In re Woodruff, 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990); In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and Ex Parte Novitski, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Claims 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (1999) *Diabetes*, Vol. 48, 2270-2276. The applicant claims a method of inducing the differentiation of a nestin-positive pancreatic stem cell into a pancreatic progenitor cell by treating a nestin-positive pancreatic stem cell with an agent selected from a group which includes IDX-1. Please note that the applicant's claims as written read on the treatment of nestin-positive pancreatic stem cells both *in vivo* and *in vitro*.

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Xu et al. teaches the administration of exendin-4 *in vivo* in rats resulting in the differentiation of new β -cells from pancreatic progenitor cells present in pancreatic ductal tissue (Xu et al., pages 2270 and 2275). While Xu et al. does not specifically teach that nestin-positive cells in the pancreas are contacted with exendin-4, pancreatic ductal tissue inherently includes nestin-positive cells. The fact that Xu teaches that ductal epithelia in the pancreas are affected by the administered exendin-4 indicates that nestin-positive cells inherently present in the pancreatic ductal tissue are contacted by the administered exendin-4. Thus, the process of inducing the differentiation of pancreatic ductal tissue by treatment with exendin-4 as taught by Xu et al. anticipates the instant invention as claimed. Please note that it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. In re Woodruff, 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990); In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and Ex Parte Novitski, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Claims 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patent No. 6,436,704 (8/20/02), hereafter referred to as Roberts et al. The applicant claims isolated nestin positive pancreatic stem cells that are not neural stem cells. The applicant further characterizes the cells as capable of differentiating into insulin-producing cells, glucagon-producing cells, or hepatocytes, or of differentiating to form pseudo-islets like aggregates.

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Roberts et al. teaches an isolated population of human pancreatic progenitor cells which are capable of differentiating into insulin or glucagon producing islet, cells, acinar cells, or ductal cells (Roberts et al., columns 19-20, claims 1-9). While Roberts et al. does teach that these cells are identifiable by the expression of a marker, Roberts does not specifically teach that the marker is nestin. However, the characteristics of the cells and the method of isolating the human pancreatic progenitor cells disclosed by Roberts is substantially similar to that used by applicants (see Roberts, column 20, claim 9, and columns 12, and 17-18). These characteristics include monolayer growth in the presence of EGF after removal of contaminating mesenchymal and stromal pancreatic cells, the ability to be multiply passaged while retaining multipotent phenotype, and the ability to differentiate into islets and other cell types. Based on these characteristics, it appears that the cell population taught by Roberts et al. is the same cell population taught by applicant. The applicant is reminded that "When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or In re Best, 195 USPQ 430, 433 (CCPA 1997). Thus, based on the structure and characteristics of the pancreatic progenitor cells isolated by Roberts et al., Roberts et al. anticipates the instant claimed nestin-positive pancreatic stem cells.

The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed

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products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989).

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE PH.D
PRIMARY EXAMINER

